

## Food and Drug Administration, HHS

## § 5.50

(2) Regional Food and Drug Directors.

(3) District Directors.

(4) The Director, St. Louis Branch.

(f) The following officials are authorized to perform the functions of the Commissioner of Food and Drugs, for drugs under their jurisdiction, pertaining to authorizing the reimportation of prescription drugs under section 801(d)(2) of the FDCA for emergency medical care:

(1) The Director, Center for Biologics Evaluation and Research (CBER) and the Director, Office of Compliance, CBER.

(2) The Director, Deputy Center Director for Review Management, and Deputy Center Director for Pharmaceutical Science, Center for Drug Evaluation and Research (CDER) and the Director and Deputy Director, Office of Compliance, CDER.

[48 FR 8441, Mar. 1, 1983, as amended at 48 FR 56946, Dec. 27, 1983; 49 FR 572, Jan. 5, 1984; 49 FR 14933, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 6518, Feb. 13, 1989; 54 FR 8317, Feb. 28, 1989; 54 FR 9034, Mar. 3, 1989; 55 FR 47053, Nov. 9, 1990; 57 FR 40318, Sept. 3, 1992; 62 FR 2555, Jan. 17, 1997; 62 FR 67271, Dec. 24, 1997]

### § 5.46 Manufacturer's resident import agents.

The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Director, Office of Compliance, CDRH, are authorized to reject manufacturer's designation of import agents under § 1005.25(b) of this chapter.

[62 FR 67271, Dec. 24, 1997]

### § 5.47 Detention of adulterated or misbranded medical devices.

The following officials are authorized to perform all the functions of the Commissioner of Food and Drugs pertaining to detention, under section 304(g) of the Federal Food, Drug, and Cosmetic Act and in accordance with § 800.55 of this chapter, of medical devices that may be adulterated or misbranded:

(a) For medical devices assigned to their respective organizations:

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH).

(2) The Director and Deputy Director, Office of Compliance, CDRH.

(3) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(4) The Director and Deputy Director, Office of Compliance, CBER.

(b) Regional Food and Drug Directors.

(c) District Directors.

(d) The Director, St. Louis Branch.

[48 FR 8442, Mar. 1, 1983, as amended at 48 FR 56947, Dec. 27, 1983; 49 FR 14933, Apr. 16, 1984; 51 FR 32452, Sept. 12, 1986; 54 FR 8317, Feb. 28, 1989; 55 FR 47053, Nov. 9, 1990; 62 FR 67271, Dec. 24, 1997]

### § 5.49 Authorization to use alternative evidence for determination of the effectiveness of medical devices.

The following officials, for medical devices assigned to their respective organizations, may authorize under section 513(a)(3)(B) of the Federal Food, Drug, and Cosmetic Act (the act) the use of valid scientific evidence (other than that prescribed by section 513(a)(3)(A) of the act) for determining the effectiveness of medical devices for the purposes of sections 513, 514, and 515 of the act:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989; 62 FR 67271, Dec. 24, 1997]

### § 5.50 Notification to petitioners of determinations made on petitions for reclassification of medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to notify petitioners of determinations made on petitions for reclassification of medical devices that are classified in class III (premarket approval) by sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act (the act) and denials of petitions for reclassification of medical devices that are submitted under

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section 513(e) of the act (except for petitions submitted in response to FEDERAL REGISTER notices initiating standard-setting under section 514(b) of the act or premarket approval under section 515(b) of the act):

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989; 54 FR 11866, Mar. 22, 1989; 62 FR 67271, Dec. 24, 1997]

## §5.51 Determination of classification of devices.

(a) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device in commercial distribution prior to May 28, 1976, pursuant to section 513(d) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER).

(b) The following officials, for devices assigned to their respective organizations, are authorized to determine the classification of a medical device first intended for commercial distribution after May 28, 1976, pursuant to section 513 (f)(1)(A) of the act:

(1) The Director and Deputy Directors, CDRH, and the Director, Deputy Directors, Chief of the Premarket Notification Section, Division and Deputy Division Directors, Associate Division Directors, and Branch Chiefs, Office of Device Evaluation, CDRH.

(2) The Director and Deputy Director, CBER.

[55 FR 6974, Feb. 27, 1990, as amended at 60 FR 2014, Jan. 6, 1995; 62 FR 67271, Dec. 24, 1997]

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## §5.52 Notification to sponsors of deficiencies in petitions for reclassification of medical devices.

The following officials, for medical devices assigned to their respective organizations, are authorized to notify sponsors of deficiencies in petitions for reclassification of medical devices submitted under sections 513(f) and 520(l) of the Federal Food, Drug, and Cosmetic Act:

(a) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH) and the Director and Deputy Directors, Office of Device Evaluation, CDRH.

(b) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

[48 FR 56947, Dec. 27, 1983, as amended at 49 FR 14933, Apr. 16, 1984; 54 FR 8317, Feb. 28, 1989; 62 FR 67271, Dec. 24, 1997]

## §5.53 Approval, disapproval, or withdrawal of approval of product development protocols and applications for premarket approval for medical devices.

(a) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, declare as complete or incomplete, or revoke product development protocols for medical devices submitted under section 515(f) of the Federal Food, Drug, and Cosmetic Act (the act):

(1) The Director and Deputy Directors, Center for Devices and Radiological Health (CDRH), the Director and Deputy Directors, Office of Device Evaluation (ODE), CDRH, and the Division Directors, ODE, CDRH.

(2) The Director and Deputy Director, Center for Biologics Evaluation and Research (CBER), and the Director and Deputy Director, Office of Biological Product Review, CBER.

(b)(1) The following officials, for medical devices assigned to their respective organizations, are authorized to approve, disapprove, or withdraw approval of applications for premarket approval for medical devices submitted under sections 515 and 520(l) of the act:

(i) The Director and Deputy Directors, CDRH, the Director and Deputy